USER MANUAL

eazy CLOT

ACTIVATED CLOT TIME MACHINE

Version : 4.4

ROBONIK®
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1. General Information

1.1. Warranty Information

Each Instrument is completely tested and guaranteed for twelve months from delivery. The warranty applies to all the mechanical and electrical parts. It is valid only for proper installation, use, and maintenance in compliance with the instructions given in this manual.

ROBONIK will at its discretion repair or replace parts, which may be found defective in the warranty period. The warranty does not include any responsibility for direct or indirect personal and/or material damages, caused by improper use or maintenance of the instrument.

Parts that are inherently subject to deterioration are excluded from the warranty. In case of defects due to misuse of the instrument, any incidental expenses like travel and man-hour service charges will be charged extra.

1.2. Technical Service

Robonik is always accessible to the customers for any kind of information about installation, use, maintenance, etc. While asking for service, please refer to this manual, and report the printed serial number on the identification label.

Only qualified technicians are entitled to fix the instrument; the user, as described in this manual, should carry out ordinary maintenance.

Robonik technical service or an authorized service center with specialized technicians, with suitable instrumentation and original spare parts are always available for extraordinary maintenance (repair), under a yearly maintenance contract or on specific demand.

1.3. Disposal instruction:

In case of removal or disposal of instrument, following instructions need to be followed

- Do not dispose in municipal waste; follow local regulations for instrument disposal.
- Plastic parts, Electronic PCBs and components can be recycled, so return back the instrument to manufacturer.

1.4. Contacts:

Manufacturer:

ROBONIK (INDIA) PVT LTD
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MAHAPE, NAVI MUMBAI –400710
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2. General Safety Warnings

2.1. Danger – warnings symbols

In this manual the following symbols are used to inform the user of the safety rules:

This symbol indicates generic danger. It means that, serious damage can occur to the operator if described precautions are not observed.

This symbol indicates HIGH ELECTRIC VOLTAGE. It is dangerous to touch any part having this label. Only qualified operators can access these components, after unplugging the instrument from the Supply.

This symbol indicates that the instrument involves the handling of samples, which can be infected (urine or human serum). In this condition, infection or contamination might occur. Pay attention to the general safety warnings when in presence of such biological substances. Use Protective clothes, gloves and glasses.

This symbol in the user manual indicates that damages to the instrument or erroneous results could occur if the given warnings are not followed.

This symbol indicates a portion, which is particularly important, and should be studied carefully.

This symbol indicates a Protective Earth or Ground terminal.

General Symbols

Symbol for “Manufacturer”

Symbol for “ IN VITRO DIAGNOSTIC MEDICAL DEVICE”

Symbol for “AUTHORISED REPRESENTATIVE IN THE EUROPEAN COMMUNITY”

2.2. Use of the instrument

The instrument has to be used for the designed purposes under specified conditions, following proper procedures and safety rules, by qualified personnel.

THIS MANUAL CONTAINS INSTRUCTIONS FOR OPERATION BY QUALIFIED PERSONNEL ONLY.

- A qualified user has to make sure that the environmental condition is suitable, the installation is correct, the use and maintenance are proper, according to the general safety rules as well as to the particular precautions described in the manual (However, he is not entitled to repair the instrument).
- A qualified technician is entitled to maintain and fix the instrument, according to the instructions given, using the original spare parts.
- Maintain room temperature and humidity as specified in the manual.
- The instrument has to be used as described in this manual. If it is not use the protection provided by the instrument may be impaired.

Alterations to the instrument are strictly prohibited. The user is liable and solely responsible for any improper modification to the instrument, and for the consequences derived as a result.

- Should the instrument need extraordinary maintenance, contact ROBONIK service or an authorized service center. Specialized technicians, who will be able to repair the instrument using original spare parts, will carry out the maintenance.
- This IVD equipment complies with the emission and immunity requirements as per IEC 61326 series.

- **Warning :** This equipment has been designed and tested to CISPER11 Class A. In a domestic environment it may cause radio interference, in which case, you may need to take measures to mitigate the interference."
- An advisory that the electromagnetic environment should be evaluated prior to operation of the device.

- **Warning :** Do not use this device in close proximity to sources of strong electromagnetic radiation (e.g. unshielded international RF sources), as these may interfere with the proper operation.

3. Introduction

3.1. Description:

eazy CLOT is an Activated clot time machine with sophisticated on board software. Its versatile and unique software supports most of the calculation required for interpretation of results. It is a reliable, high precision machine. It is intended for in vitro diagnostic use.

3.2. Special Features

- Designed to perform all routine tests such as PT, APTT, TT, FIB and clotting factors.
- Results are both printed and displayed in seconds and in concentration.
- Data is printed and stored with RATIO and INR values.
- Prints and stores calibration graph.
- Dry block incubator for 37 degree centigrade with multi timer.
- Facility to enter clinic name
- Uniform mixing of Sample & Reagent with magnetic stirrer.

3.3. Specifications

Measuring System	Photometric
Optical measurement	Photodiode
Cuvette Volume (Minimum Measurement Volume)	150 µl
Sample & reagent mixing	With magnetic stirrer
Dry block incubator Number of cuvette Holders Temperature Timer	 10 + 1 Test tube holder 37^0c 2 channels for programming incubation time
Light source	LED
Warm Up Time	90 secs.
Display	Four line LCD, back lit, 4 X 20 characters
Printer	Built – in thermal printer, 20 column
Memory	32 KB Non Volatile RAM, Battery backup supporting 35 open tests
Analysis mode	CLOT TIME, INR (PT) MULTI STD (FIB)
Results displayed in	Seconds Ratio INR (automatically calculated) Concentration
RS232 Serial Port	2400 baud, 1 start, 8 data, 1 stop, no parity bits
Power Wattage Voltage	 50 Watts 115 – 230 Volts ± 50 / 60 Hz.
Operating position	On horizontal flat, rigid and vibration free surface
Operating conditions Temperature Relative humidity	 From + 18^0 c to 35^0 c Up to 85 %
Storage conditions Temperature Relative humidity	 From -10^0 c to 60^0 c Up to 85 %
Enclosure	ABS Fire retardant
Size (cms)	20 X 30 X 10 (l X b X h)
Weight (Approx)	3 Kgs.

4. *Packing, Transport and Storage*

4.1. General warnings

Instrument has to be decontaminated before packing for transportation.

4.2. Packing

Packaging is needed whenever it is to be transported or shipped by courier or other means.

To pack the instrument follow the instructions as below described:

- Decontaminate the instrument as explained IN Decontamination chapter (Refer Index for page no.) of this manual.
- Place the instrument into the original packaging box; Instrument has to be properly protected by plastic protective material. Put copy of safety clearance certificate (copy of Safety Clearance certificate is attached at the end of this manual)
- Mark the package with address, instrument identification and warning labels.

4.3. Instrument transportation

The transportation of the instrument in unpacked condition must be limited within the room where it is used, to avoid damage.

4.4. Storage of the instrument

Before storing the instrument for a long period, pack it carefully as described above and store indoors. Relative humidity has to be less than 85%, and temperature between -10^0 c to 60^0 c

5. Installation and start-up instructions

5.1. Installation

Step 1: Unpacking instructions
Unpack the instrument. Follow the symbols shown on outer packaging .
Check accessories as per packing list dispatch with the instrument.
Kindly store all packing materials so as to use it to repack and ship for maintenance or servicing.

NOTE: The user manual should be carefully read before startup to ensure an error free operation.

Step 2: Placing the instrument

The instrument has to be placed on a level bench.
Room temperature has to be between 18 and 35ºc with a relative humidity below 85%.
Protect it from direct sunshine

Step 3: Power supply requirements

Once the instrument has been placed, plug it into a power source by the locally available approved plug-in cable. Power cord should be CE, CSA, and UL marked.

Voltage : 115-230 V ± 10% 60-50Hz.

Step 4: Protective Grounding

Warning: Please make sure that electrical power source is properly grounded.

5.2. Start Up Instruction :

Step 1: Switch on the instrument. The instrument will display the model name.

The instrument initializes all the parameters internally, and carries out a power on self-test. It then displays 'ROBONIK' and the time indicating that initialization is complete. If a printer is enabled, model name, the time, and the date will be printed.

If the correct date and time are not displayed, switch off the instrument and switch ON again.

The instrument is now in IDLE mode, and ready for use.

Step 2 : Thermal printer

The eazy CLOT comes with built-in 20 columns Thermal Printer. User has to take proper care to handle this delicate instrument.

SOME OF THE TIPS FOR CAREFUL USAGE OF PRINTER ARE AS FOLLOWS

1. Do not pull the paper when loaded.
2. Lift the paper lever carefully and load the paper.
3. Keep the instrument clean and dust free.

eazy CLOT gives line feed automatically whenever it is necessary for clear reading like

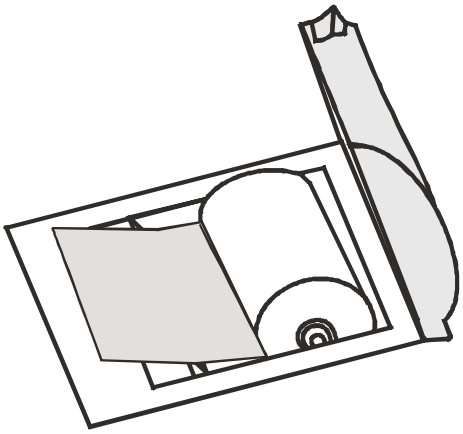
a. While powering on.
b. In between character lines.

However user also can give additional line feed to move the paper forward by a character line.

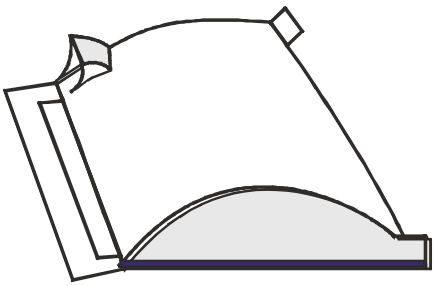
How to insert the paper

Insert the thermal paper roll by placing the sensitive side facing down. The sensitive paper side is recognizable by its smoother face.

Before inserting the paper



After inserting the paper



Step 3: Printer setting operations

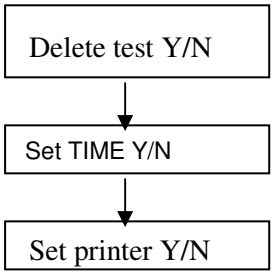
Press MENU key under Programming Mode.
Incase of any problems in thermal printer following message will displayed

"SET PRINTER PR ENTER"		Check for paper and printer cover and press
"SKIP PRINTER PR YES"	:	ENTER again to start printer.

User may operate the instrument by disabling the printer.
(press "YES" to disable the printer after above message)

To Set Printer again use following steps.

1) Press **FUNC** key

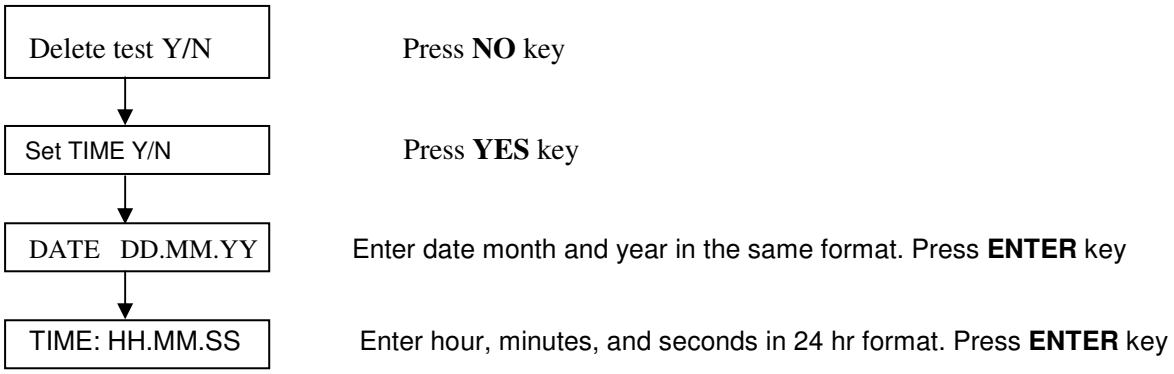


Step 4: Keyboard check.

Check key board by pressing MENU key first and all other keys later, one should get a beep and either alpha numerical or numerical should appear on display

Step 5: Setting Date and Time
Setting of date and time can be done with the help of FUNC key

Press **FUNC** key


Delete test Y/N
Press NO key
Set TIME Y/N
Press YES key
DATE DD.MM.YY
Enter date month and year in the same format. Press ENTER key
TIME: HH.MM.SS
Enter hour, minutes, and seconds in 24 hr format. Press ENTER key

The instrument goes back to idle position

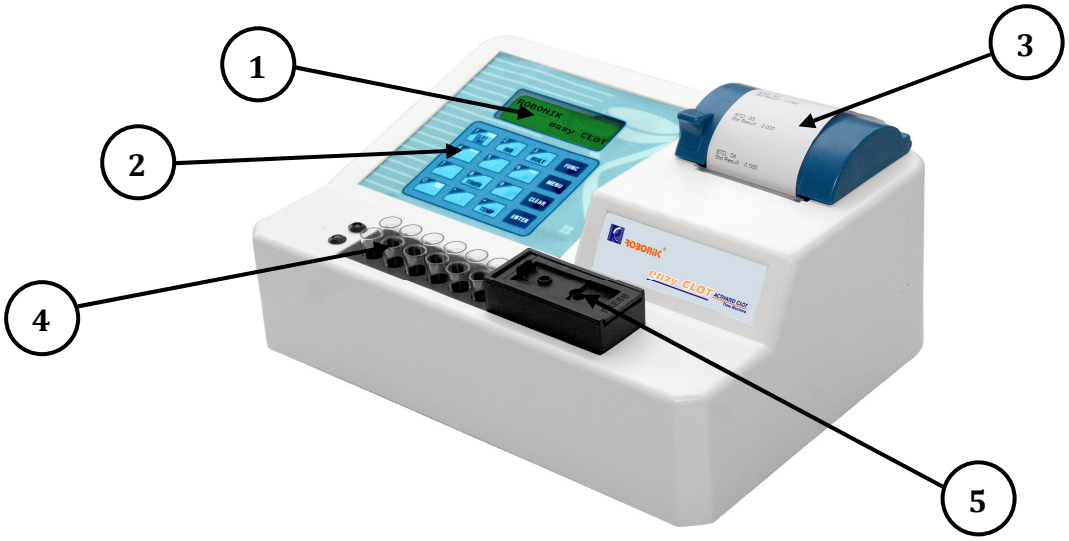
6. Instrument Description

Components of different views of the below pictured instrument:

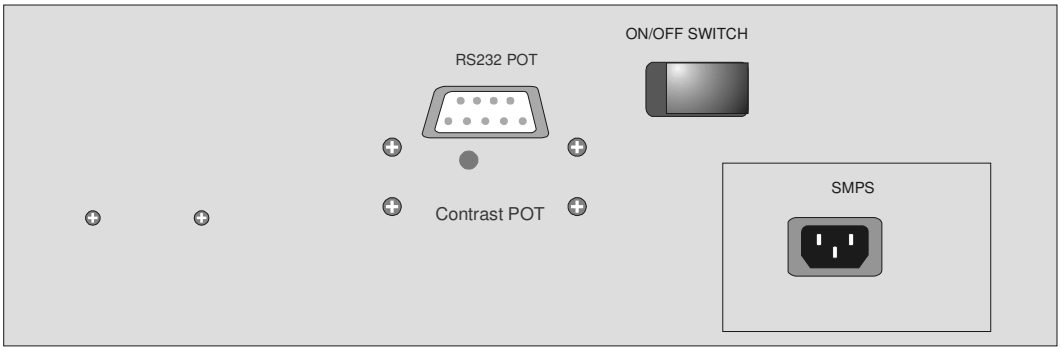
6.1. Perspective View

Front view

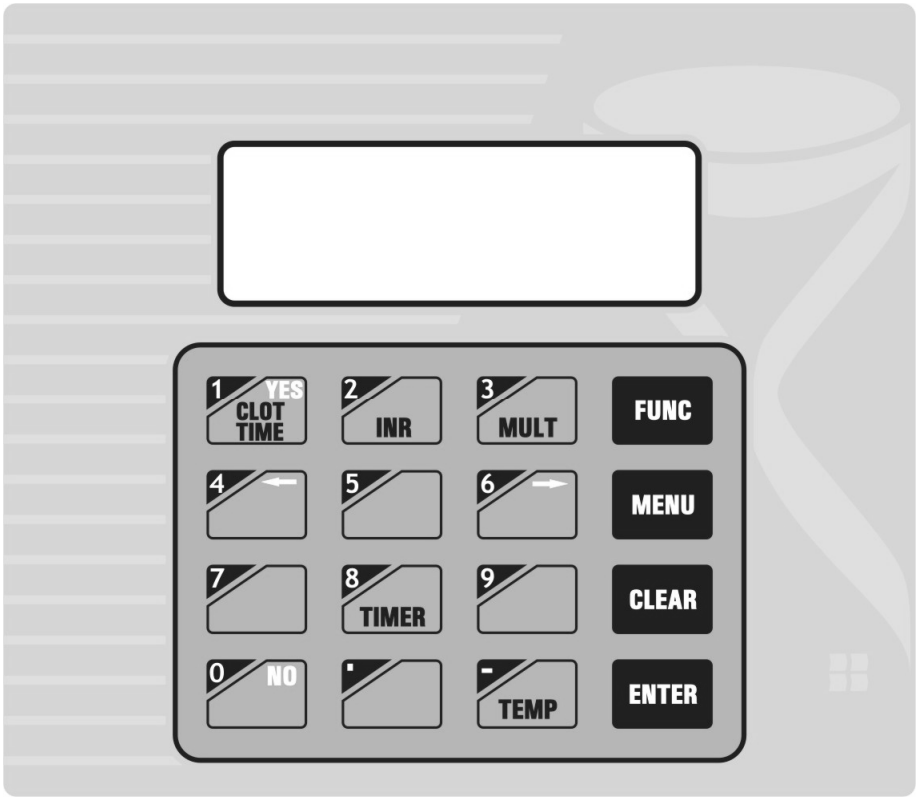
1. Display,
2. Alphanumerical keypad
3. Printer
4. Incubation Block
5. Measurement Chamber



Rear View



6.2. Keypad



6.3. Dispensing Holes Description :

- Press on the right side of the measurement chamber as shown in Fig1

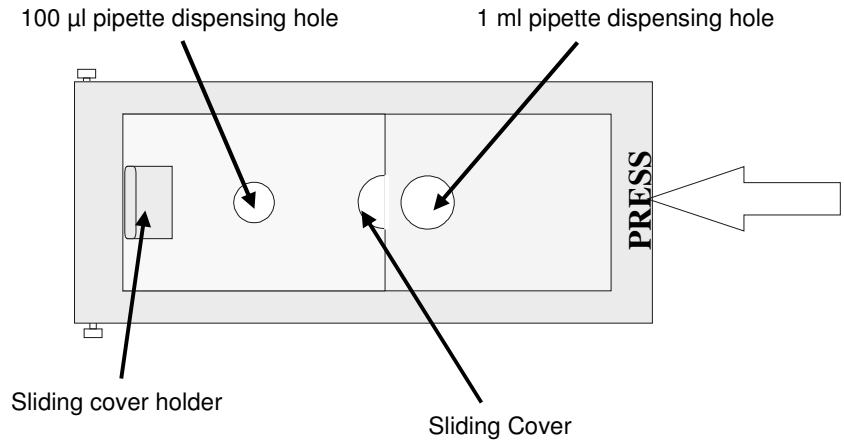


Fig. 1

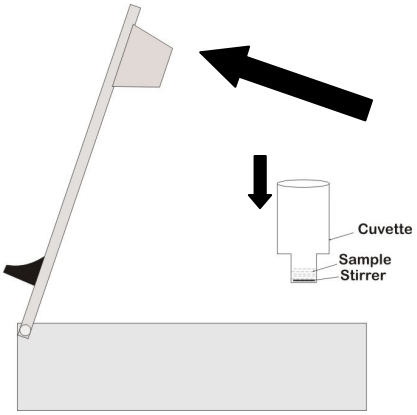
6.4. Operating Procedure:

Refer chapter 9 for operating Modes. Follow the below steps when

Display will Show **"PLACE CUVETTE"**

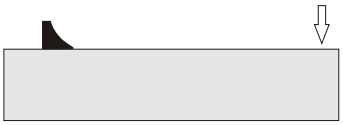
1) Lift the Chamber cover as shown in the figure (Fig.2) below.
2) Put the cuvette in the cuvette holder inside the chamber as shown in the figure (Fig.2) **(*Cuvette has to be inserted completely).**
3) Ensure stirrer inside the cuvette before placing the cuvette in measurement chamber.
4) Ensure the required quantity of sample in cuvette as per Reagent Pack Insert.

Fig. 2



5) Lock the cover by pressing down ward as shown below

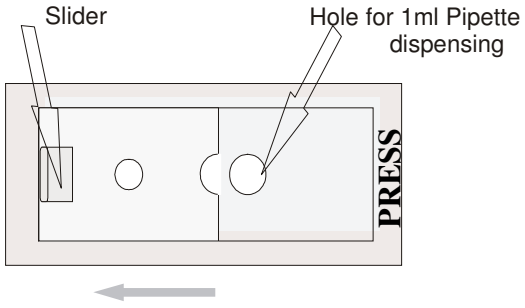
Fig. 3



Display will Show **"Dispense Reagent"**

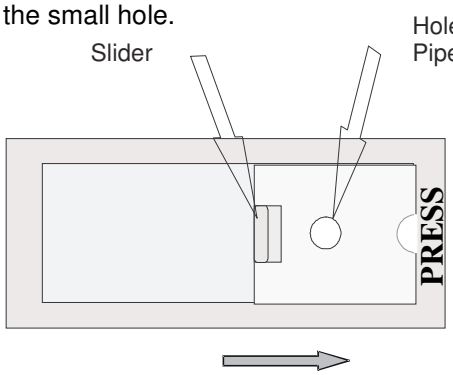
6) **Reagent adding procedure:**
If **1ml pipette** is used for dispensing reagent, then Shift the slider on the left side and put the Reagent through the big hole.

Fig. 4



If **100/50µl pipette** is used for dispensing reagent then shift the slider on the right side and put the reagent through the small hole.

Fig. 5



7) While putting the Reagent insert the pipette straight in to the dispensing hole. *Ref. Fig. 6*

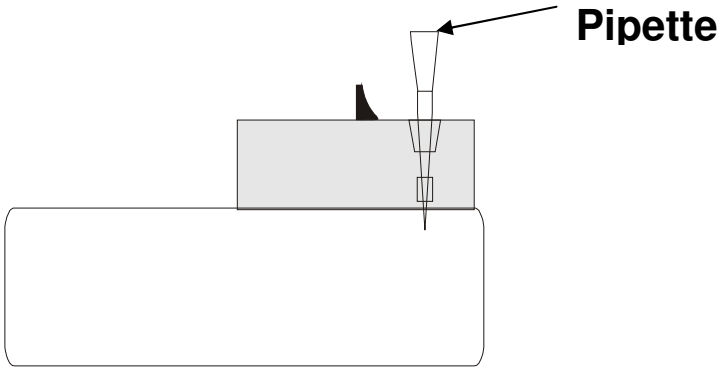


Fig. 6

8) Display will show the time **"3, 2, 1"**

When it displays 1 it gives the beep.

Dispense the reagent when it gives the beep.

9) **Display will show message** **"PLEASE WAIT"**

Indicating the measurement has started.

After clot detection this message will disappear and instrument will show the clotting time.

7. Precautions

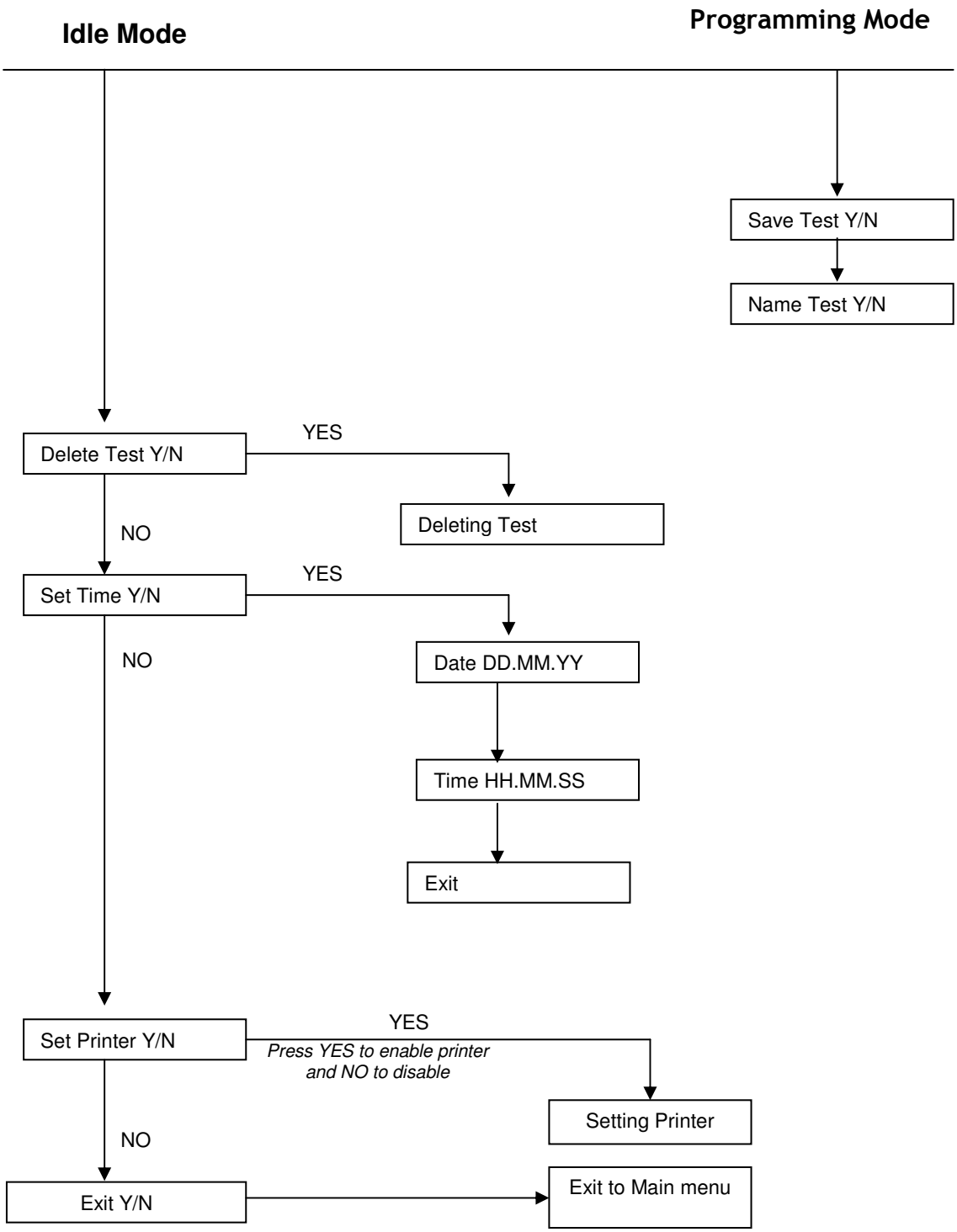
- Keep the place dry and clean.
- Check all the grounding wires properly.
- Use original packaging for transportation.
- Use clean Cuvettes.
- If results are not reproducible check for the bubbles within reaction mixture and take corrective action.
- Avoid getting bubbles within the reaction mixture, which may lead to erroneous result.
- Insert pipette tips straight down into the Cuvette and then dispense the reagent.

- Use preferably yellow and blue tips of good quality, for dispensing Reagent.
- Refer to pack insert with the Reagent and follow instruction of reagent manufacturer.
- For routine screening procedures use total of 150 µl volume.

- During critical assays when factor / factors concentration is depleted (During therapeutic dose adjustment) use total volume of 300 µl instead of 150µl to minimize CV.
- Cuvettes are specially design to read both micro and macro volumes.

8. General Operations

8.1. PRESS FUNC KEY



8.2. Menu Key

This key is used to select the test numbers .

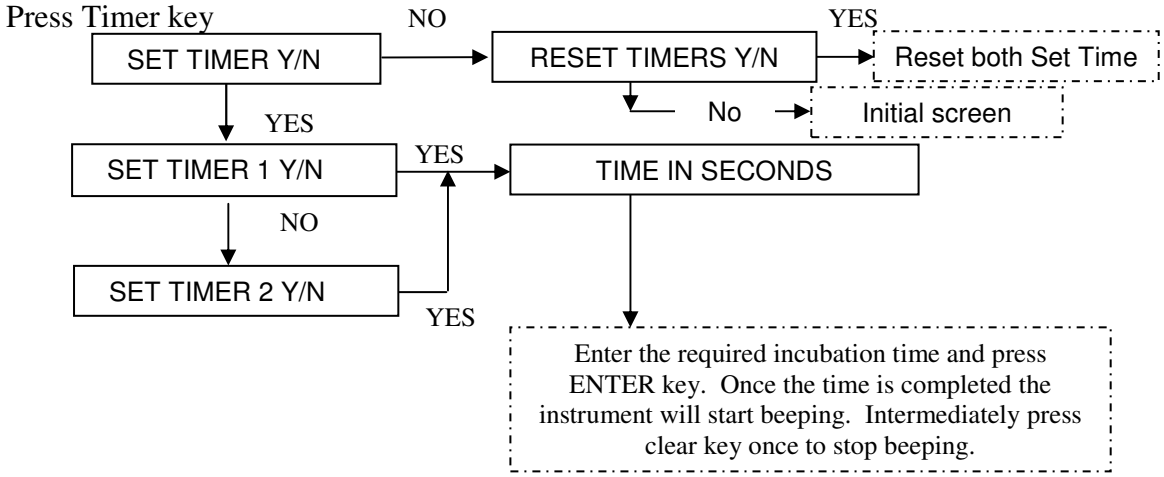
8.3. CLEAR Key

Press twice to initialize the instrument. Under data entry mode it will clear the entered data while pressing once.

8.4. ENTER Key

This key is used to complete the command or data entry.

8.5. TIMER KEY (No 8)

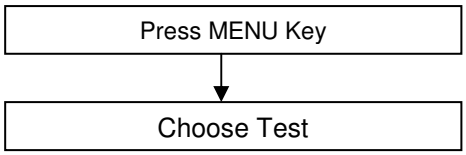


8.6. Saving Test

To save the programmed test under any programming Mode. Press FUNC key

Display	How to operate
Save Test Y/N	Press **YES** Key
Yes	
Name Tests Y/N	Press **YES** Kev to Enter Name
No → Save Test without name	
Yes	Test Number will be printed on the paper
ABCDEFGHIJKLMN	Select **Arrow Keys** (4 & 6) to select Alphabets by moving curser
	Press **Enter** after selection and proceed
	Press **Enter twice** at last alphabet
Exit	

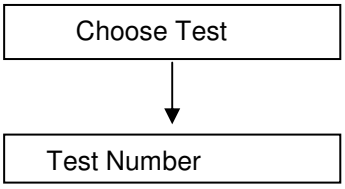
8.7. Lamp Amplitude



Enter **128** Press Enter Key

Lamp amplitude will displayed on screen and can take printout.
It should be between 3 to 8

8.8. Listing of saved test

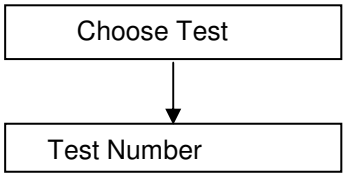


Press **MENU** Key

Enter **129** and press ENTER key.

The instrument will print a list of all saved tests.

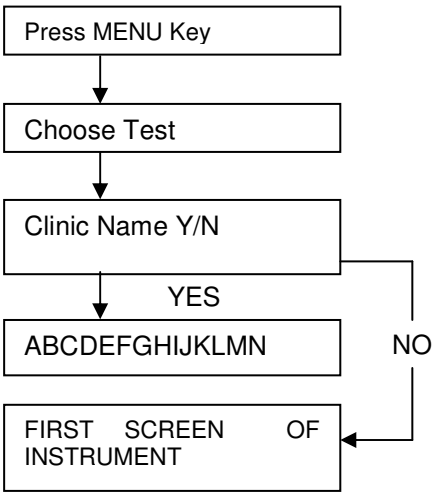
Recalling of saved test



Press **MENU** Key

Enter the **test number** to be recalled

8.9. To Enter clinic name :



Enter 132 press Enter Key

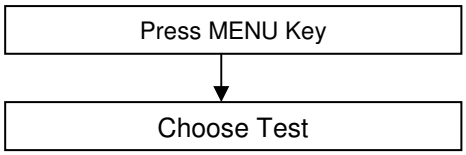
Select **Arrow Keys** (4 & 6) to select Alphabets by moving curser

Press **Enter** after selection and proceed

Press **Enter twice** at last alphabet

a maximum number of 15 characters can be entered.

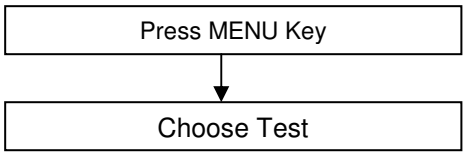
8.10. Motor ON check



Enter **199** Press Enter Key

To check continuous rotation of stirrer.

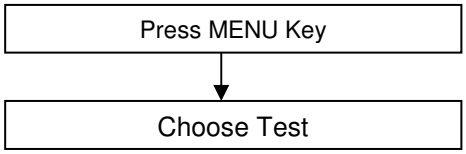
8.11. Deleting all Tests



Enter **200** Press Enter Key
Programmed memory of all tests gets erased

To delete particular test, press menu key and select that particular test and press ENTER to delete it.

8.12. Selection of Language



Enter **254** Press Enter Key

Language option Y/N will displayed on screen .with following options.

LANGUAGE OPTION 1=EN=ENGLISH 2=GERMAN, 3=SPANISH, 4=FRENCH
To select the language press the **number** and **ENTER** key.

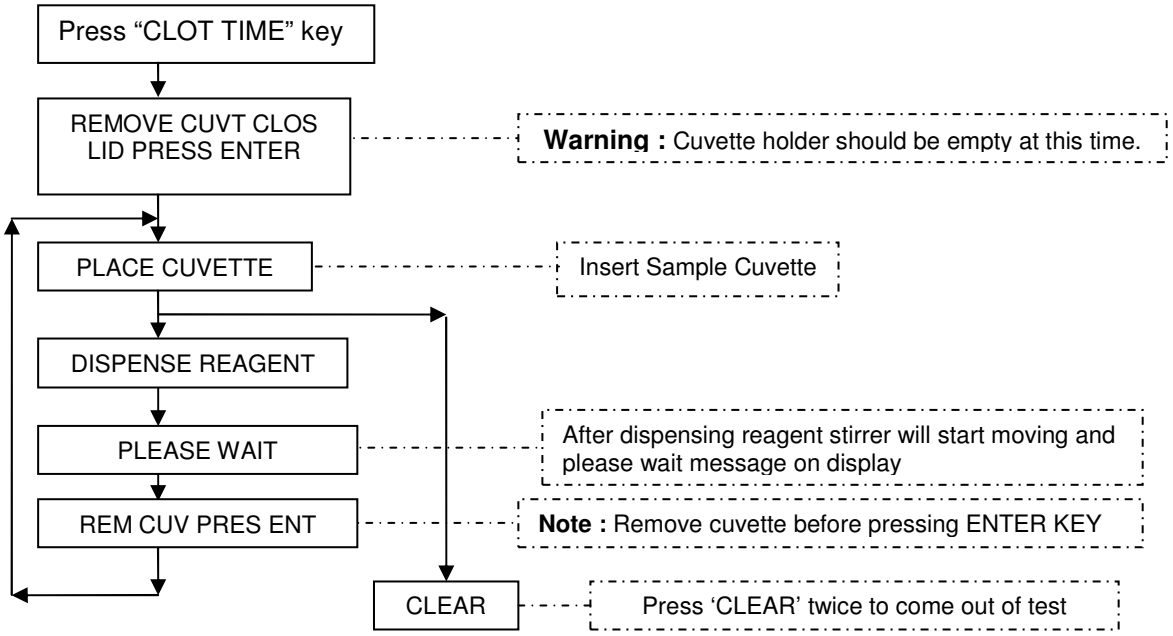
8.13. List of Test Numbers

Test Numbers	Use
128	Lamp Amplitude
129	Listing of Save Tests
132	To Enter Clinic Name
199	Continuous movement of Stirrer can be Observed.
200	To delete all the Tests.
254	To Select Language

9. Programming Modes

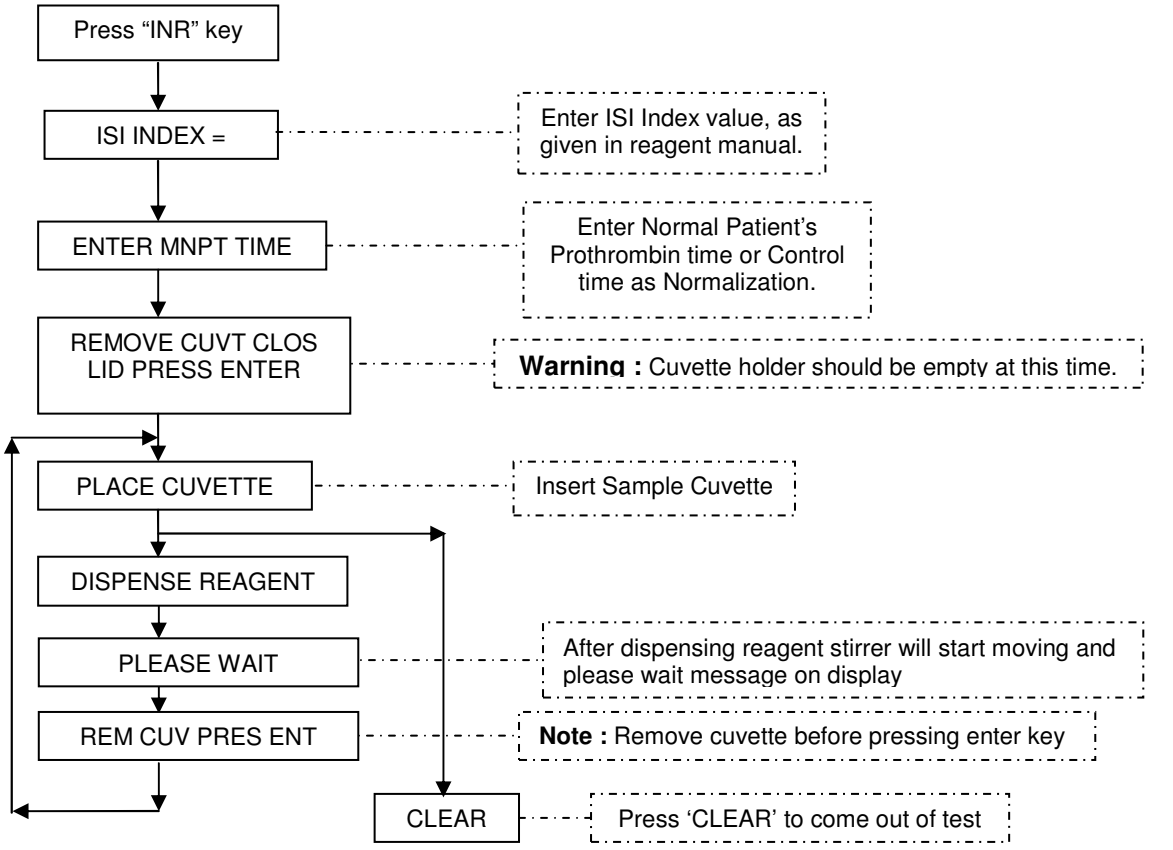
9.1. Clot Time Mode:

Instrument measures only time there is no calculation, this mode is used to can Run APTT, PT Tests.


Press "CLOT TIME" key
REMOVE CUVT CLOS LID PRESS ENTER
Warning : Cuvette holder should be empty at this time.
PLACE CUVETTE
Insert Sample Cuvette
DISPENSE REAGENT
PLEASE WAIT
After dispensing reagent stirrer will start moving and please wait message on display
REM CUV PRES ENT
Note : Remove cuvette before pressing ENTER KEY
CLEAR
Press 'CLEAR' twice to come out of test

9.2. INR Mode / PT Mode:

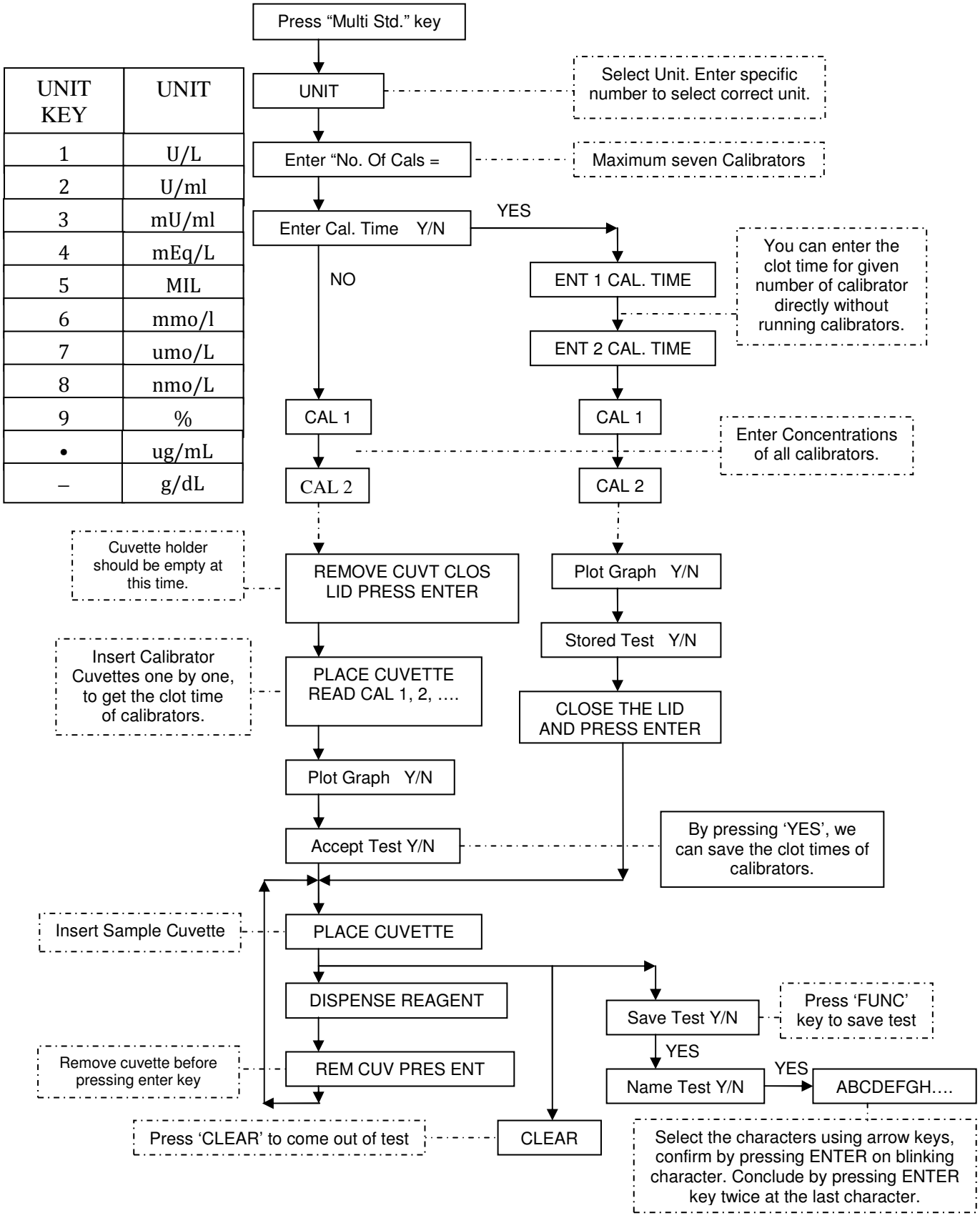
Instrument measures clot time of sample and by calculation gives INR ratio. INR mode is used to run the PT test. (Prothrombin Time).


Press "INR" key
ISI INDEX =
Enter ISI Index value, as given in reagent manual.
ENTER MNPT TIME
Enter Normal Patient's Prothrombin time or Control time as Normalization.
REMOVE CUVT CLOS LID PRESS ENTER
Warning : Cuvette holder should be empty at this time.
PLACE CUVETTE
Insert Sample Cuvette
DISPENSE REAGENT
PLEASE WAIT
After dispensing reagent stirrer will start moving and please wait message on display
REM CUV PRES ENT
Note : Remove cuvette before pressing enter key
CLEAR
Press 'CLEAR' to come out of test

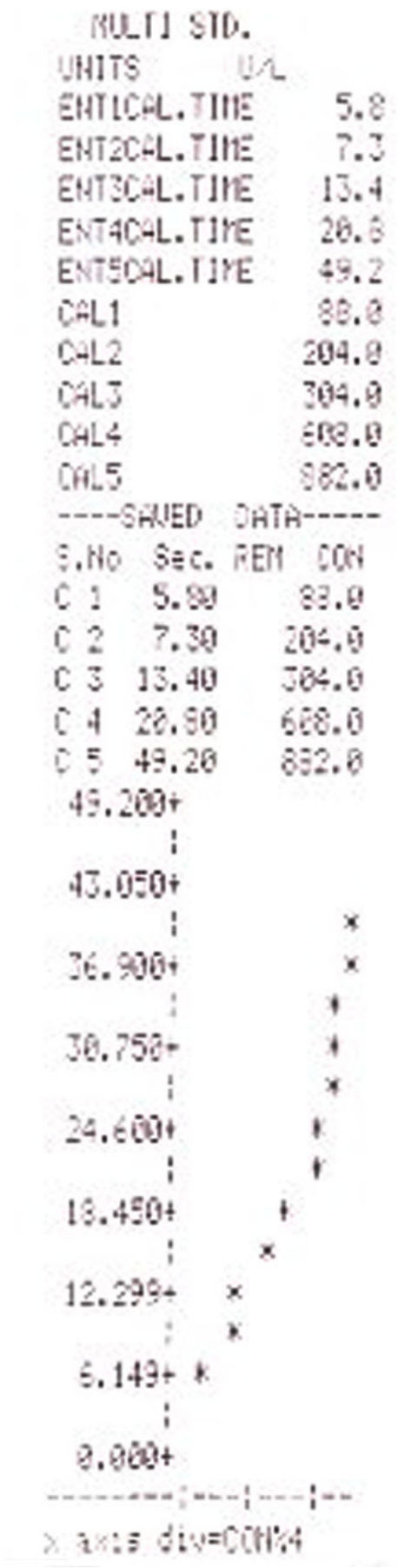
9.3. Multi Standard Mode / Fibrinogen Mode:

In multi standard mode maximum 7 calibrators can be selected. It plots the graphs of clot time v/s concentration based on best fit (Linear) method with Log-Log scale. This mode is used to run fibrinogen, and factor assay test.

UNIT KEY	UNIT
1	U/L
2	U/ml
3	mU/ml
4	mEq/L
5	MIL
6	mmo/l
7	umo/L
8	nmo/L
9	%
•	ug/mL
–	g/dL


Press "Multi Std." key
UNIT
Select Unit. Enter specific number to select correct unit.
Enter "No. Of Cals =
Maximum seven Calibrators
Enter Cal. Time Y/N
YES
NO
ENT 1 CAL. TIME
You can enter the clot time for given number of calibrator directly without running calibrators.
ENT 2 CAL. TIME
CAL 1
CAL 1
Enter Concentrations of all calibrators.
CAL 2
CAL 2
Cuvette holder should be empty at this time.
REMOVE CUVT CLOS LID PRESS ENTER
Plot Graph Y/N
Stored Test Y/N
Insert Calibrator Cuvettes one by one, to get the clot time of calibrators.
PLACE CUVETTE READ CAL 1, 2, ...
CLOSE THE LID AND PRESS ENTER
Plot Graph Y/N
Accept Test Y/N
By pressing 'YES', we can save the clot times of calibrators.
Insert Sample Cuvette
PLACE CUVETTE
DISPENSE REAGENT
Save Test Y/N
Press 'FUNC' key to save test
YES
Remove cuvette before pressing enter key
REM CUV PRES ENT
YES
Name Test Y/N
ABCDEFGH....
Press 'CLEAR' to come out of test
CLEAR
Select the characters using arrow keys, confirm by pressing ENTER on blinking character. Conclude by pressing ENTER key twice at the last character.

Sample Graph Printout in Multistandard Mode:



10. Trouble Shooting

ERROR MESSAGES	CORRECTIVE ACTION
"Memory over range "	If Number of saved tests exceeds 40 tests then delete the unwanted tests and save the test.
"SKIP PRIN. PR.YES" "SET PRI & PR.ENT "	1) Check printer paper or printer cover properly placed. 2) Refer to Printer setting in Start Up Instructions.
"Lamp Intensity Poor "	1) Check whether cuvette is present while referencing. (when display shows CLOSE THE LID AND PRESS ENTER) **NOTE**: While referencing cuvette should not be there. 2) Choose test 128, to see the lamp amplitude value. It should not be below 3. 000

Other ERRORS	CORRECTIVE ACTION
No consistency in Reading	1. Check stirrer inside the cuvette. 2. Follow the reagent volume as specified in Pack Insert. 3. Follow Reagent dispensing procedure carefully Put the pipette straight and remove immediately in straight direction –do not shake. (Cuvette should not shake from its position)
Random readings stops at 1.0 sec.	1. Follow Reagent dispensing procedure carefully Put the pipette straight and remove immediately in straight direction –do not shake 2. Check cuvette is inserted completely; It should not be loose in cuvette holder.

11. Decontamination

11.1. Decontamination Procedure

If the instrument is to be shipped after being exposed to potentially hazardous material, it should be decontaminated. The following procedure outlines how to decontaminate the instrument before packaging and shipment.

11.2. Purpose of Decontamination

Decontamination minimizes the risk to all who come in contact with the instrument during shipping, handling, and servicing.

11.3. General Considerations

- Any laboratory instrument that has been used for clinical analysis is considered a biohazard and should be decontaminated prior to handling. Intact skin is generally considered an effective barrier against infectious Organisms; however, small abrasions and cuts may not be always being visible. Prophylactic gloves must be worn when handling instruments that have not been decontaminated. Gloved hands should be considered contaminated at all times and must be kept away from eyes, mouth and nose at all times.

- Mucous membranes are considered prime entry routes form infectious agents. Wear eye protection and a surgical mask when there is a possibility of aerosols.

- Eating and drinking while decontaminating instruments is not advisable.

11.4. Procedure

- A solution of .5% Sodium Hypo Chlorite (NaOCL) solution (Bleach) is used. Commercial bleach is 5% NaOCL; household bleach is 3% NaOCL. When using commercial bleach, use a 10:1 mixture; if using household bleach, a 6:1 mixture is required. This is a caustic solution. It is important to wear gloves and eye protection when handling it.

- Wipe down the carrier and all exposed surfaces of the unit with the bleach solution. Remove the top shroud of the instrument and wipe down the top surface of the instrument base, as well as the inside of the top shroud.

- Reassemble the unit and discard the used gloves and towels.

12. SAFETY CLEARANCE CERTIFICATE

Please complete all information requests on this form prior to returning the instrument to the manufacturer or your local distributor for servicing, repairs or return. Thank you for your co-operation.

Customer _____ Contact _____

Address _____ Position _____

_____ Dept _____

_____ Tel: _____

_____

Country _____ Fax: _____

Post Code _____

Model No. _____ Serial No. _____

Accessories
Return _____

Date of Purchase (if known) _____

Report Fault _____

_____

_____

_____

Has the equipment been exposed to any of the following: (*delete as applicable)

a) Blood, body fluids, pathological specimens *YES/NO
If YES, please specify _____

_____

b) Other Biohazard *YES/NO
If YES, Please specify _____

_____